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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC **PLAINTIFF'S NOTICE OF FILING PROPOSED SUPPLEMENTAL JURY INSTRUCTIONS**

In accordance with the Court's direction, Plaintiff Sherr-Una Booker files and provides notice of the proposed jury charges she submitted in open court on March 27, 2018. For ease of reference, Plaintiff has numbered her new requests to charge (with the exception to her proposed revision to the Court's superseding cause instruction) sequentially from those previously submitted by Plaintiff.

PLAINTIFF'S PROPOSED REVISION OF COURT'S INSTRUCTION RE SUPERSEDING CAUSE – DR. KANG

Bard contends that the intervening action of Dr. Brandon Kang constituted a superseding cause of Ms. Booker's injuries.

A superseding cause is the cause of Ms. Booker's injury that breaks the chain of causation between Bard, on the one hand, and Ms. Booker's injuries, on the other hand. If you find that Dr. Kang's action was the superseding cause of one or more of Ms. Booker's injuries, then Bard cannot be held liable for that injury.

For Bard to prove that Dr. Kang's intervening action was a superseding cause, Bard must show that his action was the sole proximate cause of Ms. Booker's injury. To make this showing, Bard must prove by a preponderance of the evidence that:

(1) Dr. Kang's action was not foreseeable by Bard,

(2) Bard did not trigger Dr. Kang's action, and

(3) Dr. Kang's action was sufficient by itself to cause the injury.

If Bard could have reasonably anticipated or foreseen the probable and natural consequences of Dr. Kang's actions, Dr. Kang's actions are not a superseding cause of Ms. Booker's injury even if Bard did not anticipate the details of his action or the injury it caused.

To constitute a superseding cause, Bard need not prove that Dr. Kang's action was wrongful or negligent.

PLAINTIFF'S REQUEST TO CHARGE NO. 18

LIMITING CHARGE MITIGATION AND COMPARATIVE FAULT/CONTRIBUTORY NEGLIGENCE

There is no contention by Bard that Ms. Booker is at fault for any of her injuries in this case.

PLAINTIFF'S REQUEST TO CHARGE NO. 19

Duty of a Medical Device Manufacturer Not to Sell Adulterated or Misbranded Medical Devices

As a medical device manufacturer, federal law prohibits Bard from selling a medical device that was adulterated or misbranded.

Source: 21 U.S.C. § 331(a) & (b)

PLAINTIFF'S REQUEST TO CHARGE NO. 20

Definition of Adulterated

A medical device is "adulterated" under federal law if its strength or quality falls below that which it purports or is represented to possess.

Source: 21 U.S.C. § 351(c).

PLAINTIFF'S REQUEST TO CHARGE NO. 21

Definition of Misbranded

A medical device is "misbranded" under federal law if its labeling is false or misleading in any detail. In determining whether the labeling or advertising is misleading you should take into account (among other things) representations made or suggested and the extent to which the labeling or advertising fails to reveal material facts given the representations or the consequences which may result from the use of the device.

Source: 21 U.S.C. § 352(a)(1) & (t); 21 U.S.C. § 321(k) & (n).

PLAINTIFF'S REQUEST TO CHARGE NO. 22

Testimony by Food and Drug Administration employees

No officer or employee of the Food and Drug Administration (FDA) shall give any testimony before any court pertaining to any function of the FDA or with respect to any information acquired in the discharge of his official duties without authorization and approval of the Commissioner of the FDA.

Source: 21 U.S.C. § 20.1(a) & (c)

PLAINTIFF'S REQUEST TO CHARGE NO. 23

FDA Limiting Instruction

The 510(k) process focuses on device equivalence, not device safety.

Bard's IVC filters are not FDA approved, they are cleared by the FDA through the 510(k) premarket notification process.

Clearance of a device through the 510(k) process does not render a finding by the FDA that the filter is safe and effective.

Any representation that creates an impression of official approval of a device because the manufacturer complied with the 510(k) premarket notification regulation is misleading and constitutes misbranding.

Source: January 29, 2018 Order [Doc. 9881]

RESPECTFULLY SUBMITTED this 28th day of March 2018.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

/s/ Deborah Yanazzo